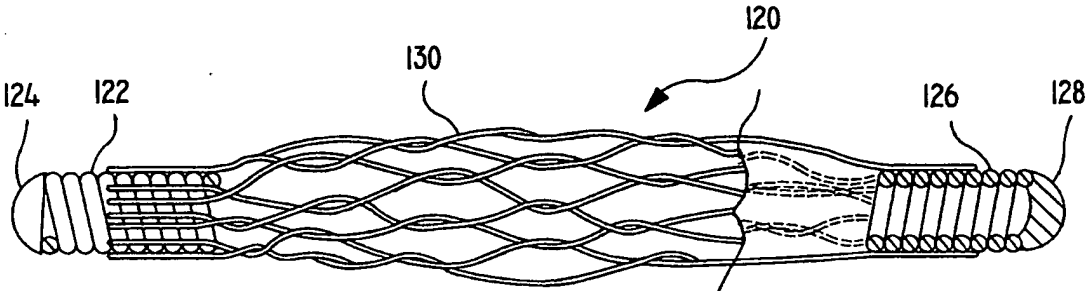




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61B 17/00	A1	(11) International Publication Number: WO 94/09705 (43) International Publication Date: 11 May 1994 (11.05.94)
(21) International Application Number: PCT/US93/10239 (22) International Filing Date: 26 October 1993 (26.10.93) (30) Priority data: 07/965,973 26 October 1992 (26.10.92) US (60) Parent Application or Grant (63) Related by Continuation US 07/965,973 (CIP) Filed on 26 October 1992 (26.10.92) (71) Applicant (for all designated States except US): TARGET THERAPEUTICS, INC. [US/US]; 47201 Lakeview Boulevard, P.O. Box 5120, Fremont, CA 94537-5120 (US).		(72) Inventors; and (75) Inventors/Applicants (for US only) : PHELPS, James, J. [US/US]; 853 Orange Avenue, Sunnyvale, CA 94087 (US). VAN, Nga, Thi [US/US]; 3583 Mauricia Avenue, Santa Clara, CA 95051 (US). (74) Agents: WHEELOCK, E., Thomas et al.; Morrison & Forster, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US). (81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: VASOOCCLUSION COIL WITH WOVEN FIBROUS TUBULAR COVERING <div style="text-align: center;">  </div> (57) Abstract This invention is in the field of vasoocclusion devices. More particularly, it relates to a vasoocclusion coil (120) which may be segmented, onto which a fibrous, woven or braided, tubular covering or element is attached.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

5

VASOOCCLUSION COIL WITH WOVEN FIBROUS TUBULAR COVERING

Field of the Invention

10

This invention is in the field of vasoocclusion devices. More particularly, it relates to a vasoocclusion coil which may be continuous or segmented, onto which a fibrous, woven or braided, tubular covering or element is attached.

15

Background of the Invention

Vasoocclusion devices are surgical implements that are placed within the vasculature of the human body, typically via a catheter, to block the flow of blood through the vessel making up that portion of the vasculature or within an aneurysm stemming from the vessel. One widely used vasoocclusive device is a helical wire coil having windings that are dimensioned to engage the walls of the vessels. Fibers may also be woven or laid crosswise through the windings to provide a substrate for clot formation and tissues growth within the chosen site. Coils having such a structure are readily commercially available.

20
25
30

U.S. Patent Number 4,994,069, to Ritchart et al., describes a vasoocclusive coil which assumes a linear helical configuration when stretched, and a folded convoluted configuration when relaxed. The coil is introduced into the human body in a stretched condition. When the coil reaches its intended site, the coil assumes

35

its relaxed condition -- which is better suited to occlude the vessel -- and restricts blood flow beyond the space that it occupies.

U.S. Patent Application Serial Number

5 07/771,013, to Chee et al., teaches a helical vasoocclusion coil to which fibrous elements are attached in such a way that they will not be dislodged from the coil. The fibrous elements enhance the ability of the coil to fill space within the vasculature and to
10 facilitate clot formation and tissue growth.

Care must be taken in creating combination fibrous coils, i.e., those containing metal coils and fibrous elements, since the fibrous elements may come off and move to vessels supplying blood to normal tissue.
15 Fibrous elements, since they are not normally radiopaque, are difficult to find and to retrieve if separated from the metallic coil. Nevertheless, it is desirable to increase the ratio of fibrous element to the metallic coil since the fibrous element increases the tendency at
20 the coil assembly to cause embolic and tissue growth.

The inventive coil assembly is desirable in that the ratio of fibrous material to metallic material is quite high, the fibrous material is held firmly in place due to the braided or woven configuration, and is
25 easily placed within the body's vasculature.

Summary of the Invention

This invention is a vasoocclusive device comprising:

30 (a) a helical coil which may be segmented, continuous, or segmented having a gap between the two end portions, but in each case having a first end and a second end;

(b) at least one fibrous woven or braided tubular element or covering attached to the exterior of the helical coil.

5 Brief Description of the Drawings

Figure 1 is a schematic depiction of an overall system for introducing the inventive devices into the vessel of a human body.

10 Figures 2-21 are side views or partial cross-sectional side views of a number of embodiments of the inventive vasoocclusive device.

Description of the Invention

15 The vasoocclusive devices of this invention may be used in a manner similar to those described in U.S. Patent Number 4,994,069. Briefly, the coil devices may be supplied in a prepackaged form in a sterile cannula which is adapted to engage the proximal end of a catheter. As is shown in Figure 1, once the catheter
20 (100) is in place within a vessel (102) -- for instance, the distal end (104) of the catheter (100) at an aneurysm (106) -- the coil-containing cannula is placed into engagement with the proximal end of the catheter and the coils are transferred from the cannula lumen into the
25 catheter lumen by exerting force on the proximal end of the coil. A flexible pusher device (108) is used to push the coil (110) through the catheter (100) to the desired coil release site. The location of the coils (110) may be observed due to the radial opacity of the metallic
30 coils. Once at the site, the coils are singularly plunged from the catheter lumen into the vessel site (106).

Figure 2 depicts one embodiment of the vasoocclusive coil of the invention, generally shown as
35 (120). The vasoocclusive device (120) has several

components: a first helical coil end (122), a cap (124),
a second helical coil end (126), a cap (128), and a
braided or woven tubular fibrous element extending from
near the termination of the first helical coil (122) and
5 to a similar position on the second coil end (126). In
this variation, the coil is segmented and has a gap
beneath the fibrous tubular element (130).

Coil ends (122) and (126), variously in this
configuration and in the others discussed herein, will
10 typically be made of a radiopaque material such as
platinum, tungsten, gold, silver, or alloys thereof, or
other suitable generally radiopaque metals which are
otherwise biologically inert. The diameter of the wire
will typically be in the range of 0.0005 and 0.005
15 inches. The resulting primary coil diameter will
normally be 0.008 to 0.018 inches. Preferably, the coil
primary diameter is 0.015 to 0.018 inches. Preferred is
a platinum-tungsten alloy forming a coil having a
diameter of 0.015 to 0.018 inches. The axial length of
20 the coil will usually be in the range of 0.5-100 cm.,
more usually 2.5 to 40 cm. The coil will typically have
10-71 windings per cm, more typically about 10-40
windings per cm the coil windings may be regular. The
fibrous woven or braided tubular member (130) may be made
25 from a biocompatible materials such as Dacron
(polyester), polyglycolic acid, polylactic acid,
fluoropolymers (polytetrafluoroethylene), nylon
(polyamide), or silk. The strands forming the braid
should be reasonably heavy, e.g., having tensile strength
30 of greater than about 0.15 pounds. The materials
mentioned, to the extent that they are thermoplastics,
may be melted or fused to the coils. Alternatively, they
may be glued or otherwise fastened to the coils.
Preferred materials are Dacron strands using the process
35 of fusing to attach the strands to the coil surface.

The caps (124) and (128) shown in Figure 1 may be independently applied materials such as glues or biocompatible solders, but typically are formed merely by melting the tips of the coils or the braided polymer.

5 The fibrous elements may be a bundle of individual fibers, e.g., between 5 and 100 fibers per fibrous bundle, preferably 20 to 30 fibers per bundle, or may be monofilaments.

Figure 3 shows another variation of the
10 inventive vasoocclusive device (120). In this variation, may be found first coil (122) and second coil (126). The tubular braid (130) in this variation extends all the way to the end of the respective coil ends. In addition to the braid extending to and being fixedly attached to the
15 end coils (122) and (126), the device lacks end caps. In this way, the vasoocclusive device may be strung on a catheter guide wire (similar in operation to that wire or rod 108 shown in Figure 1) and may be pushed off the end of the wire using a coaxial sleeve.

20 Figure 4 shows a further variation of the inventive device (120) in which the braid (130) extends from near the ends of the respective coil ends (122) and 126. In this variation, wire (132) is placed between the end caps (124) and (128). The wire (132) may be wound in
25 any configuration including straight coils or C-shaped coils or the like. The wire (132) is typically made of stainless steel but may be made of other appropriate materials including shape memory alloys such as Nitinol. Nitinol wire having the proper transition temperature
30 allows the device to be introduced through the catheter in a linear fashion and upon raising the temperature of the vasoocclusive coil to body temperature, the wire assumes its pre-selected shape.

Figure 5 shows another variation of the
35 inventive vasoocclusive device (134). In this variation

- 6 -

the coil (136) is not segmented but is continuous from a first end (138) to a second end (140). First end cap (142) is found on the first end of the coil and a second cap (144) is found on the second end. The braided or
5 woven tubular element (130) is found on the outside of the coil (136) and runs substantially from the first end (138) of the coil (136) to the second end (140). Coil (136) may be given a specific shape prior to its introduction into the catheter. For instance, the coil
10 may be pre-shaped to form a "C" when ejected from the tip of the catheter lumen. During its traverse through the lumen, it would be constrained by the catheter or maintain a linear shape. Caps (142) and (144) may be omitted from this design as desired.

15 Figure 6 shows another variation of the inventive vasoocclusive coil having a first coil end (122) with a first cap (124) second coil end (126) with a cap (128). This device obviously has a segmented coil portion. The braided or woven tubular covering (146)
20 extends from near the tip of the first coil end (122) to the second cap (128). In addition, the tubular member has tassels (148) which extend past the end of the coil. This feature provides additional occlusion area and adds very little to the volume of the device as it passes
25 through the catheter lumen.

Figure 7 shows a vasoocclusive device very similar in design to the Figure 3 device. It differs in that the braided covering does not extend to the ends of first coil end (122) nor second coil end (126). As is
30 apparent from Figure 7, the coil is a two-piece segment with a gap between the two segments.

Figure 8 shows a vasoocclusive device in which the braid (160) is loosely woven and is attached only at one end (162) of the braid. Figure 9 shows a similar

35

device in which multiple fibrous braids (162) are attached to a single coil.

Figure 10 shows a variation of the vasoocclusive device in which a number of independent
5 braided sections (162) are included on a single continuous coil (164). The braid is attached to the coil at multiple locations in this variation.

Figure 11 shows a device in which a fibrous element overlies the coil (164). The fibrous braided
10 portion (166) is constructed to have exposed fiber elements (168) sticking out from the fiber tubular member. This variation enhances the ability of the device to effectively fill the space at the target within patient's vasculature.

Figure 12 shows a device in which the fibrous outerlying element (170) is axially compressed prior to
15 installation upon the coil so that it bulges (172) from the middle of the coil (164). This bulging allows the combination to occupy more space once it is placed within the patient's vasculature.
20

Figures 13 through 19 show a variety of complex coil shapes covered with a braided or woven covering. The coil cores in these variations are found, e.g., in U.S. Patent 4,994,069 mentioned above. These coil
25 typically only assume their convoluted configurations upon ejection from the catheter tip.

Figure 13 shows a simple multi-loop coil (174) having a small primary diameter but a large secondary diameter (150). The secondary diameter (150) is often
30 chosen to match that of the inside diameter (176) of the vascular site. The presence of the braided material on the outside of the coil helps to occlude that site. Similarly, Figure 14 shows a coil (178) having a configuration as that of Figure 13 except that it is
35 given an added amount of twist to allow assumption of a

large symmetrical flower-like design upon its relaxation after leaving the tip of the catheter. This configuration, with its braided cover (180), permits filling of a large vascular space with a coil and which
5 filling is enhanced by the braided or woven covering.

Figure 15 shows still a further variation of the invention. In this variation, the coil (182) has been pre-crimped (152) so to precondition the coil to form a random configuration upon its relaxation. Again,
10 the braided or woven covering (184) enhances the ability of this random coil (186) to occlude the site at which it is placed.

Figure 16 show a variation of the invention having two secondary diameters. The coil is
15 preconditioned so that it has a larger secondary diameter (154) and a smaller secondary diameter (156). In this way, the larger secondary diameter (154) may be chosen to match that of the vascular site to be treated. The smaller secondary diameter (156) therefore ends up in the
20 middle area of the targeted vascular region. The placement of the portion of the coil having a smaller secondary diameter away from the vessel wall enhances the propensity of the coil to occlude the site. The presence of the braided or woven covering (188) on the outside of
25 the coil further augments the tendency of the coil-braid combination towards production of an embolus.

Figure 17 show a variation of the invention shown in Figure 14. In this instance the relaxed and braid (190) covered coil (192) forms only a "cloverleaf".
30 This is believed to be somewhat more controllable from a physical placement point of view and consequently is of great use to attending physicians. Again the presence of the braided covering enhances the coil assembly's facility to produce occluding material.

Figure 18 shows a similar two-loop coil (194) design with braid (196) and Figure 19 shows the C-shaped coil (198) design with braid (200) mentioned above. The Figure 17 and 18 devices may be sized in such a fashion
5 that they nest tightly within the vascular pocket or vessel which is to be occluded by the device.

Figure 20 shows a variation in which a single outer woven or braided covering 158 encloses a number of individual coils.

10 Figure 21 shows another variation in which coils 160 are used to join a number of braided covers 150. Again, the figure 20 and 21 are variations of a type which allows a large number of coils and braids linked together to be placed upon a guide wire and
15 injected from the catheter with relative ease. These configurations allow the occlusion device to be randomly jumbled at the site so to efficiently occlude the vascular opening.

20 Modification of the above-described variations of carrying out the invention that are obvious to those of skill in the fields of medical device design generally, and vasoocclusion devices specifically, are
25 intended to be within the scope of the following claims.

30

35

WE CLAIM AS OUR INVENTION:

1. A vasoocclusive device comprising:
 - a. a helical coil having a multiplicity of windings and having a first end and a second end;
 - 5 b. at least one fibrous woven tubular member extending coaxially about at least a portion of the helical coil and adhering to the helical coil at at least one location on the coil.

where the device is of a size which may be

10 introduced through the lumen of a vascular catheter.
2. The device of claim 1 in which the helical coil is segmented.
- 15 3. The device of claim 1 in which the helical coil is continuous.
4. The device of claim 1 in which the fibrous woven tubular member is braided.
- 20 5. The device of claim 4 in which the fibrous woven tubular member has an inside and an outside and wherein the device additionally comprises tassels extending beyond the outside of said tubular member.
- 25 6. The device of claim 2 in which the fibrous woven tubular member is braided.
7. The device of claim 6 in which the fibrous woven tubular element has an inside and an outside and wherein the device additionally comprises tassels extending beyond the outside of said tubular member.
- 30 8. The device of claim 3 in which the fibrous woven tubular member is braided.
- 35

-11-

9. The device of claim 8 in which the fibrous woven tubular element has an inside and an outside and wherein the device additionally comprises tassels extending beyond the outside of said tubular member.

5

10. The device of claim 8 where the helical coil assumes a random configuration when utilized.

11. The device of claim 8 when the helical
10 coil assumes a cloverleaf configuration where relaxed.

12. The device at claim 8 where the helical coil assumes a regular coiled configuration where relaxed.

15

13. The device of claim 8 where the helical coil assumes a coiled shape having two secondary diameters where relaxed.

14. The device of claim 1 including multiple fibrous woven tubular members.

15. The device of claim 14 where the tubular members have a first end and a second end.

25

16. The device of claim 15 where the tubular member first ends are attached to the helical coil.

17. The device of claim 16 where the tubular
30 member second end is also attached to the helical coil.

18. The device of claim 17 where the tubular members are axially compressed on the axis between their first and second ends and bulge from the coils.

35

-12-

19. The device of claim 1 where the device has a diameter of 0.008 to 0.018 inches.

20. A vasoocclusive device comprising:

5 a. a helical coil having a multiplicity of windings comprising wire having a wire diameter between 0.0005 and 0.005 inches and said coil having a first end and a second end;

10 b. at least one fibrous woven tubular member extending coaxially about at least a portion of the helical coil and adhering to the helical coil on at least one location on the coil.

15 21. The device of claim 20 in which the helical coil is segmented.

22. The device of claim 20 in which the helical coil is continuous.

20 23. The device of claim 20 in which the fibrous woven tubular member is braided.

25 24. The device of claim 23 in which the fibrous woven tubular member has an inside and an outside and wherein the device additionally comprises tassels extending beyond the outside of said tubular member.

25 25. The device of claim 23 in which the fibrous woven tubular member is braided.

30

26. The device of claim 25 in which the fibrous woven tubular member has an inside and an outside and wherein the device additionally comprises tassels extending beyond the outside of said tubular member.

35

-13-

27. The device of claim 22 in which the fibrous woven tubular member is braided.

5 28. The device of claim 27 in which the fibrous woven tubular member has an inside and an outside and wherein the device additionally comprises tassels extending beyond the outside of said tubular member.

10 29. The device of claim 27 where the helical coil assumes a random configuration where utilized.

30. The device of claim 27 where the helical coil assumes a cloverleaf configuration where relaxed.

15 31. The device at claim 27 where the helical coil assumes a regular coiled configuration where relaxed.

20 32. The device of claim 27 where the helical coil assumes a coiled shape having two secondary diameters where relaxed.

25 33. The device of claim 20 including multiple fibrous woven tubular members.

34. The device of claim 33 where the tubular members have a first end and a second end.

30 35. The device of claim 34 where the tubular members' first ends are attached to the helical coil.

35 36. The device of claim 35 where the tubular members' second ends are also attached to the helical coil.

37. The device of claim 36 where the tubular members are axially compressed on the axis between their first and second ends and bulge from the coils.

5 38. The device of claim 20 where the device has a diameter of 0.008 to 0.018 inches.

10

15

20

25

30

35

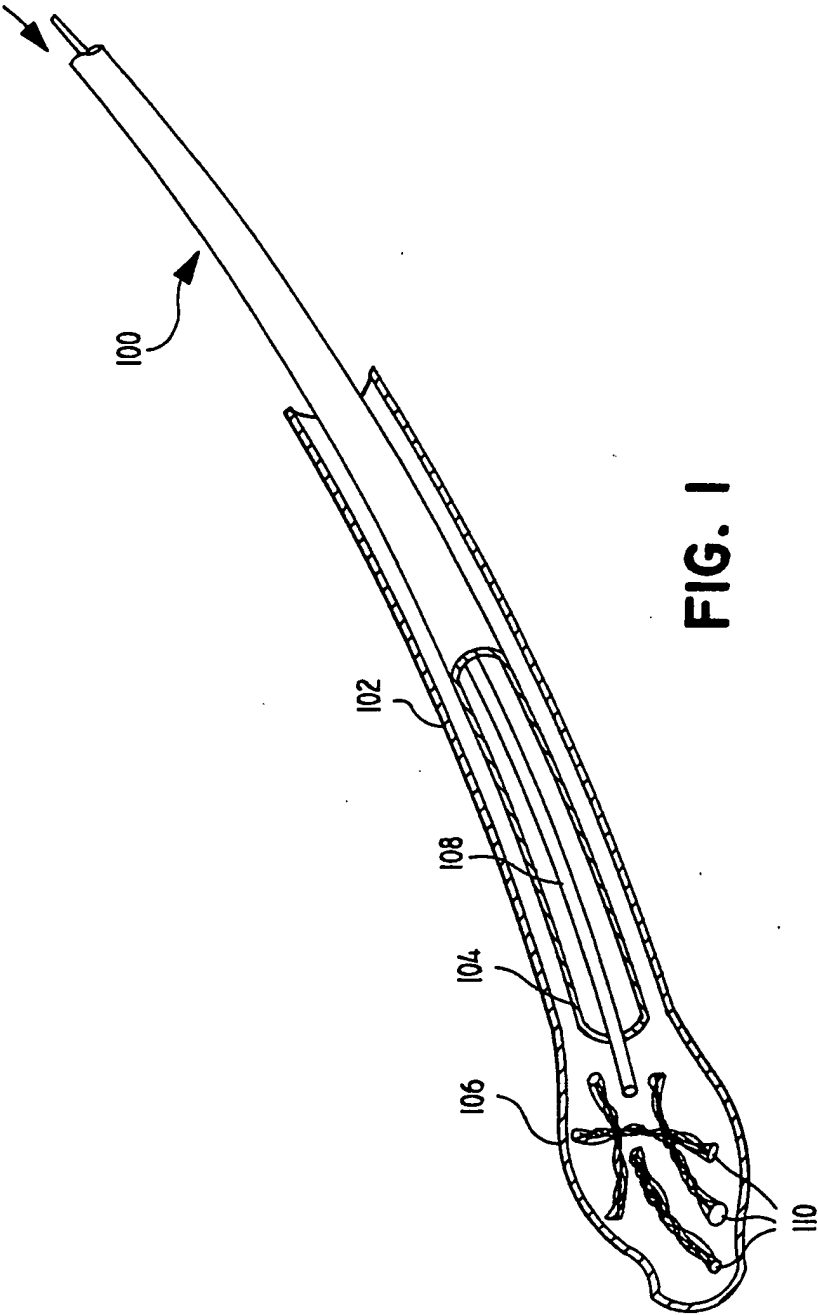


FIG. 1

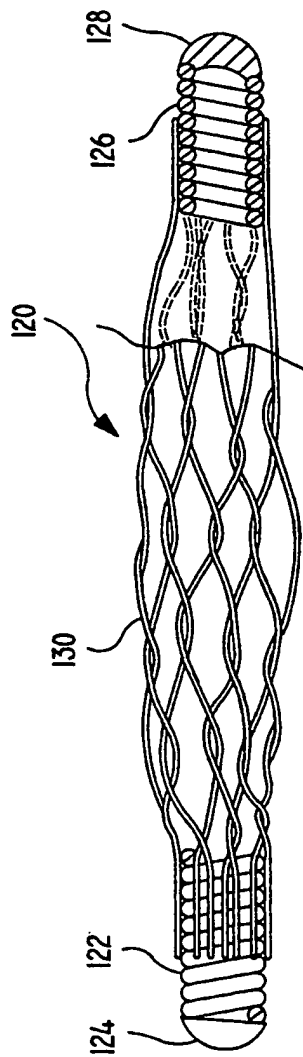


FIG. 2

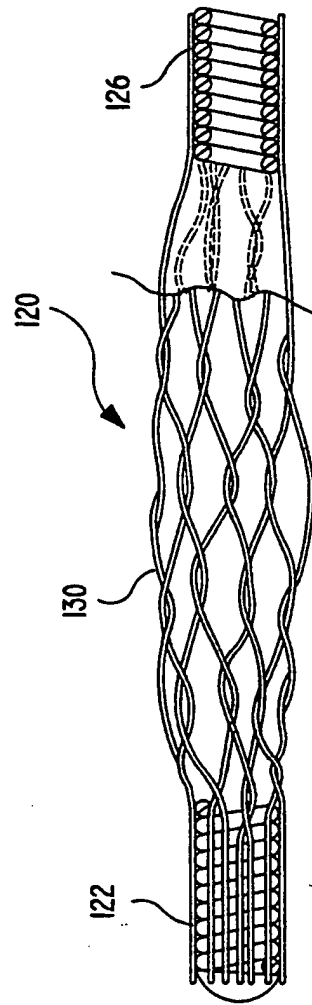


FIG. 3

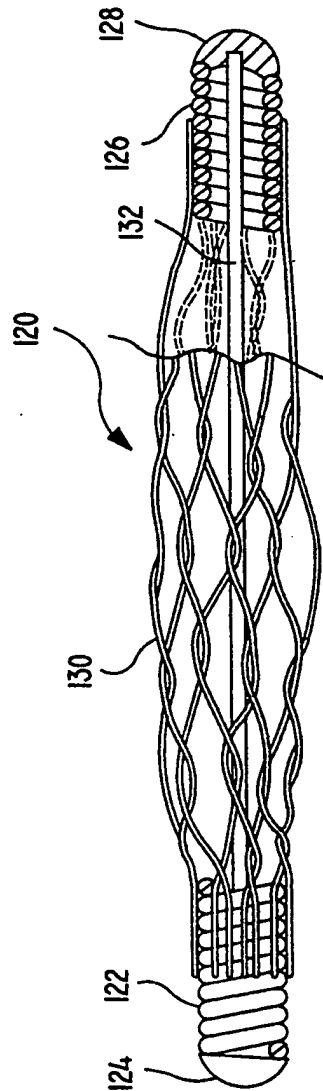


FIG. 4

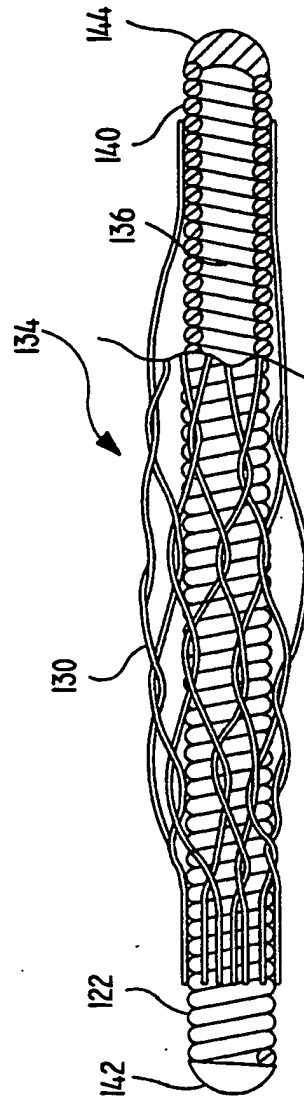


FIG. 5

4/7

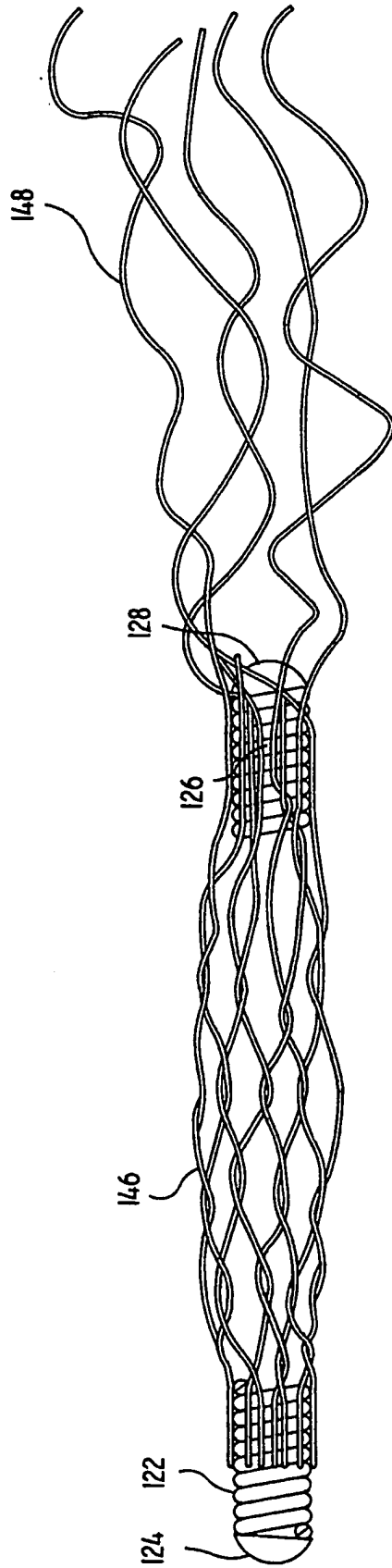


FIG. 6

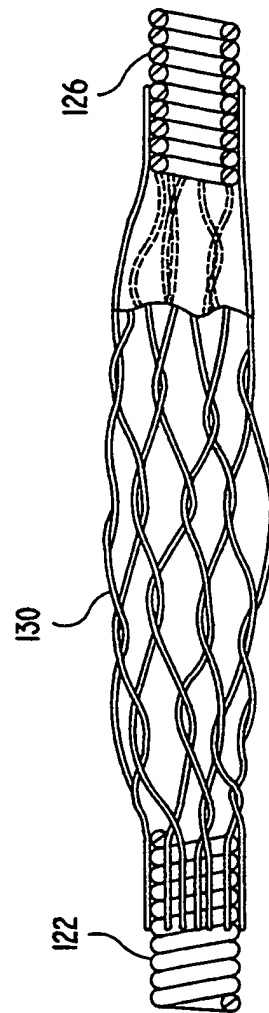


FIG. 7

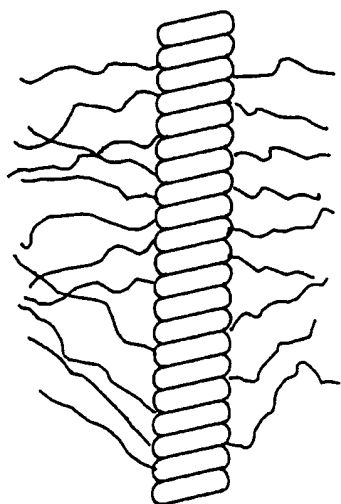


FIG. 8

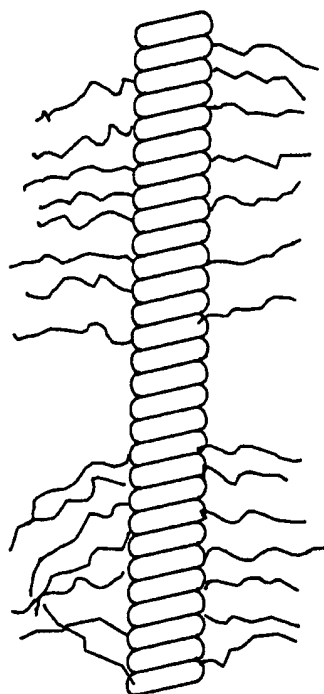


FIG. 9

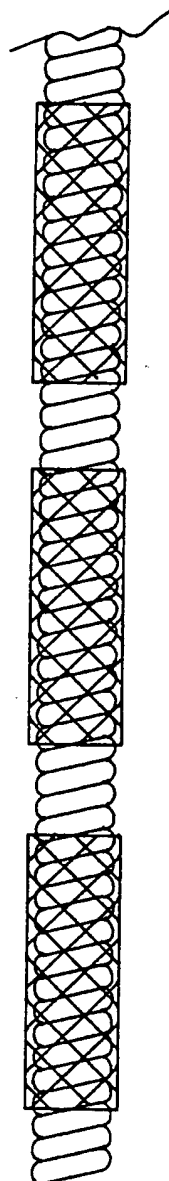


FIG. 10

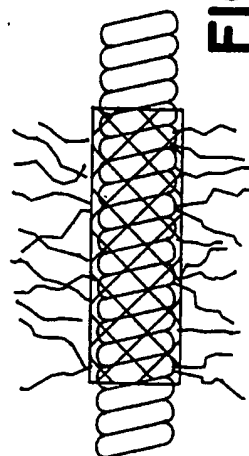


FIG. 11

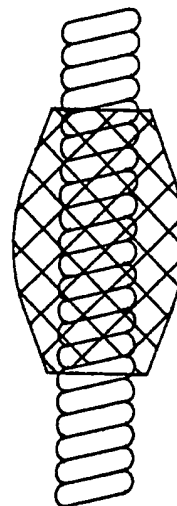


FIG. 12

6/7

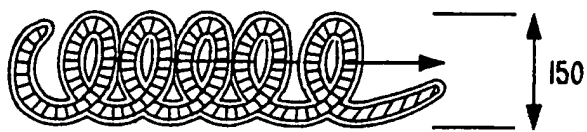


FIG. 13

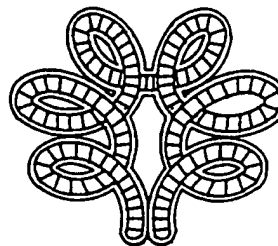


FIG. 14

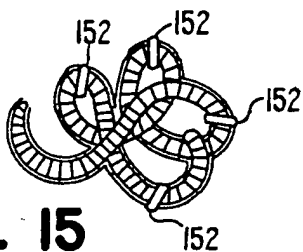


FIG. 15

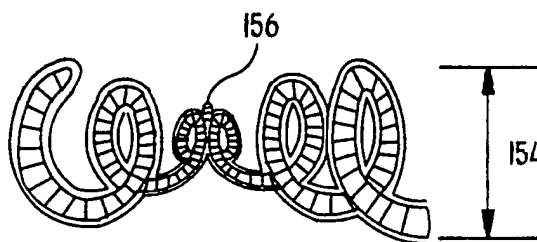


FIG. 16

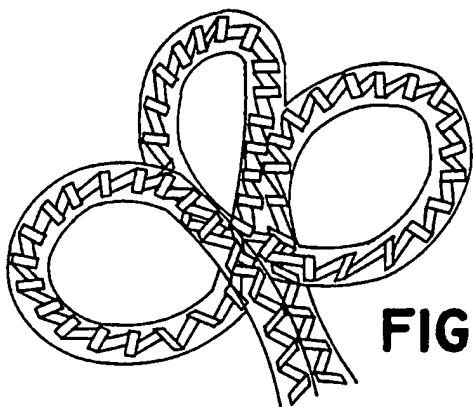


FIG. 17

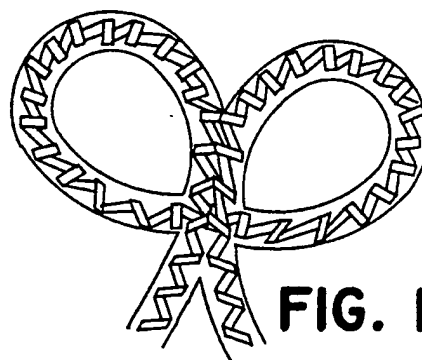


FIG. 18

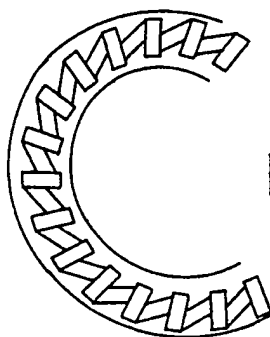


FIG. 19

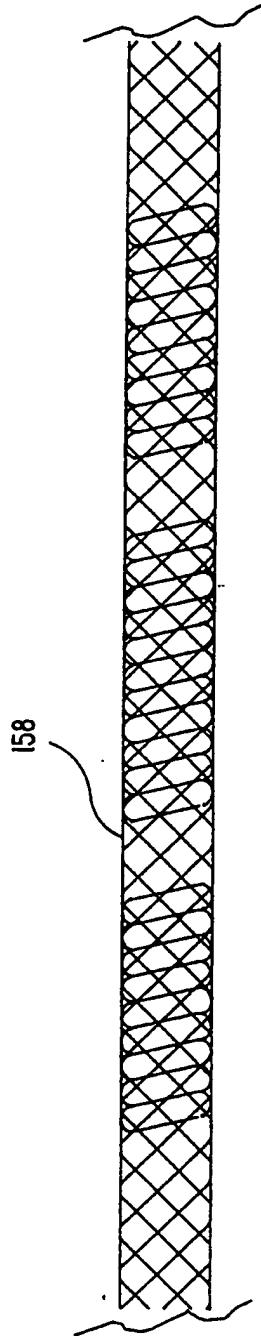


FIG. 20

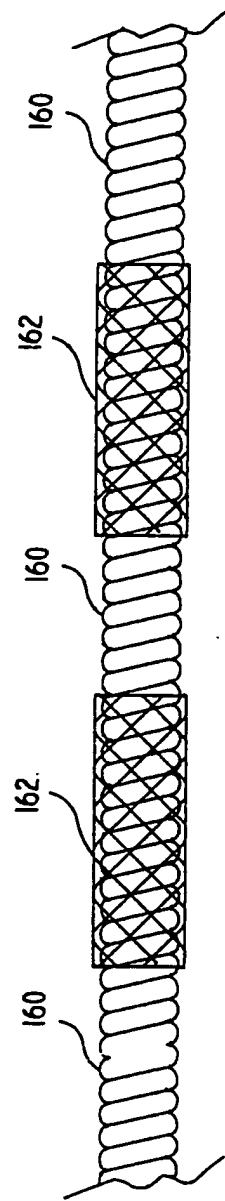


FIG. 21

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US93/10239

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A 61B 17/00

US CL : 606/151; 623/1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/108, 151, 191, 194, 198; 604/107, 105, 104; 623/1, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NoneElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
None

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,151,105, (Kwan-Gett), 29 September 1992. See entire document.	1-17, 19-36, 38
Y	US, A, 5,078,726, (Kreamer), 07 January 1992. See Fig. 1	2, 4, 6-8, 21, 23, 25, 27
Y	US, A, 3,687,129, (Nuwayser), 29 August 1972. See entire document.	5, 7, 9, 24, 26, 28
Y	US, A, 4,994,069, (Ritchart et al.), 19 February 1991. See entire document.	10, 11, 13, 29, 30, 32
Y	US, A, 5,064,435, (Porter), 12 November 1991. See entire document.	14-17, 33-36

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principles or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

09 MARCH 1994

Date of mailing of the international search report

11 APR 1994

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

TAMARA L. GRAYSAY

Telephone No. (703) 308-0858

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US93/10239

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- P Y	US, A, 5,211,658, (Clouse), 18 May 1993. See entire document.	1, 3, 12 ----- 48, 19, 20, 22, 23, 25, 27, 31, 38
A	EP, A, 0 464 755, (Kubo et al.), 08 January 1992. See Figs. 1, 6.	None
A	EP, A, 0 385 925, (Bittman et al.), 05 September 1990.	None
A	US, A, 5,108,407, (Geremia et al.), 28 April 1992. See column 7, lines 1-14.	None
A	FR, A, 2 671 482, (Seguin), 17 July 1992.	None